6

Docket No.: 532792001001

REMARKS/ARGUMENTS

In an Office Action dated June 3, 2004, claims 20-33, 39, 40, 42-46, 52, 54, and 55 were rejected, and claims 41 and 53 were objected to. By this amendment, claims 20, 31, 39, and 52 have been amended. Claims 1-19, 34-38, and 47-51 are canceled. New claims 56-59 have been added. Claims 20-33, 39-46, and 52-59 will be pending after entry of these amendments. Applicants request reconsideration of the pending claims in view of the present amendment and following remarks.

Claims 20, 31, 39, and 52 have been amended to add a recitation specifying percent identity to SEQ ID NO:1. Support for the percent identity specified in claims 20, 31, 39 and 52 may be found on page 28, lines 23-32.

New claims 56-59 have been added with this amendment. Support for the hybridization wash conditions in claims 56-59 may be found on page 9, lines 15-23 of the Specification.

Withdrawn Objections/Rejections

Applicants thank the Examiner for withdrawing the objection to the specification and the rejection of claims 26,31-33, 39 and 41 under 35 USC 112, second paragraph.

Claim Rejections - 35 USC § 112, second paragraph

The Examiner has rejected claims 20-30, 39-40, 42-46, 52, and 55 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner has asserted that the term "CDR1" is not known in the art and therefore fails to identify the claimed nucleic acid molecule. The Examiner has further indicated that amending claims 20 and 39 to recited SEQ ID NO: would obviate the rejection.

Applicants respectfully disagree with the Examiner's grounds for rejection. One of skill in the art would have no difficulty in recognizing the scope of the term "CDR1." CDR1 is the acronym for the constitutive disease resistance 1 polypeptide. In addition, the polynucleotide or nucleic acid encoding the polypeptide must have 75% identity to SEQ ID NO:1 given that claims 20, 39, and 52 have been amended to include this limitation. Furthermore, claims 21-30, 40, 42-46,

7

Docket No.: 532792001001

and 55 depend from the amended claims and thereby include the recitation. When determining whether the metes and bounds of a term used in a claim are clear, one must refer to the knowledge of one of skill in the art as well as the disclosure in the specification. In this case, the specification clearly sets forth the metes and bounds of a constitutive disease resistance 1 polypeptide. The specification discusses the functional and structural characteristics of a constitutive disease resistance 1 polypeptide in the specification on page 6, line 1 through page 11, line 21. Further characterization may be found in the specification in Examples 2-14. Given the abundant description in the specification of the structural and functional characteristics of a constitutive disease resistance 1 polypeptide and the recitation that the polynucleotide or nucleic acid encoding the CDR 1 polypeptide is at least 75% identical to SEQ ID NO:1, one of skill in the art would be apprised of the metes and bounds of the invention as claimed.

In light of the above, Applicants respectfully request that the Examiner withdraw the rejection of claims 20-30, 39-40, 42-46, 52, and 55 based upon 35 U.S.C. § 112, second paragraph.

Claim Rejections - 35 USC § 112, first paragraph, Enablement

The Examiner has rejected claims 20-33, 39-40, 42-46, 52, and 54-55 under 35 U.S.C. 112, first paragraph, as failing to enable one of skill in the art to make and use the claimed invention commensurate in scope with the claims.

Applicants respectfully disagree. The specification provides more that adequate support to enable one of skill in the art to make and use the claimed invention commensurate in scope with the claimed invention. The Examiner has asserted that undue experimentation would be required. However, as indicated in *In re Wands*, undue experimentation is evaluated based upon eight factors, including the quantity of experimentation, the amount of direction or guidance provided, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims. In the present application, undue experimentation is not required for one of skill in the art to make and use the invention commensurate in scope with the claims. Application of the *Wands* factors to the claimed invention clearly supports this. The first *Wand* factor is the quantity of experimentation necessary. The quantity of experimentation is not undue. The molecular biology

SEP. 3. 2004 11:48AM MOFO 28TH FL

NO. 051 P. 10

Docket No.: 532792001001

Application No.: 10/016,358 ·

testing is routine in the art.

8

techniques for generating the vectors are routine and therefore not undue experimentation. The techniques for plant transformation are also routine and therefore not undue experimentation. Identification of nucleic acids or polynucleotides that have 75% identity to SEQ ID NO:1 is a routine matter given the wide availability of programs for sequence alignment such as BLAST. Finally, screening for the claimed function of plants with increased disease resistance is routine and therefore not undue experimentation. It is does not matter that it may take a fair amount of work to screen through multiple non-exemplified sequences to find those that function. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. All of the construct generation and

The second Wands factor is the amount of direction or guidance provided. As discussed with regard to the first Wands factor, the nature of the experimentation is all routine, so the techniques used need not be disclosed, and yet they are disclosed in actual working examples. Furthermore, page 27, line 20 to page 28, line 31, discusses methods of identifying additional CDR1 genes by hybridization and by routine methods of alignment of nucleic acid and protein sequences. Such alignments can provide further information regarding the structural elements that are likely required for function and will indicate some of the mutations that may be accommodated without affecting the function. Thus, there is a fair amount of guidance provided as how to identify additional sequences.

The third Wands factor is the present or absence of working examples. Applicants have taught actual working examples of the CDR 1 gene. Example 7 on page 37, line 18 to page 38, line 23 teaches the isolation of a CDR 1 gene. Furthermore, the other examples provide an abundant disclosure characterizing the functional and structural characteristics of the expression of CDR 1, including resistance to pests, influence on the expression of related genes, increase in salicylic acid, and release of a 4.5 kDa polypeptide into the intercellular fluids. Thus Applicants have provided actual working examples.

9

Docket No.: 532792001001

The fourth Wands factor is the nature of the invention. In this case, making and using the invention requires only routine molecular biology techniques and is a matter of routine testing of sequences related to those disclosed.

The fifth Wands factor is the state of the prior art. The state of the art is high. As of the priority date of July 14, 1998, molecular biology techniques were well worked out and included a high degree of automation owing to genome sequencing, etc. Thus, one of skill in the art is capable of screening through large numbers of random and site-directed mutants in order to identify additional CDR 1 nucleic acids and polypeptides.

The sixth Wands factor is the relative skill of those in the art. The skill in the art is quite high. Plant transformation is typically done by graduate level research scientists or higher. Such research scientists are well versed in the molecular biology and screening techniques required by the claimed invention.

The seventh Wands factor is the predictability or unpredictability of the art. While the effect of mutations in genes cannot be predicted with one hundred percent accuracy, the working examples combined with the ability to align the disclosed sequence with other sequences coming out of the many genome sequencing projects provides some degree of predictability that will provide one of skill in the art a starting point.

The eighth Wands factor is the breadth of the claims. The claims are not unduly broad given the disclosure of the exemplary gene sequence and the abundant functional and structure characterization of the gene and its expression. Further, as discussed above in the SYNOPSIS EXAMPLE provided by the USPTO, one of skill in the art would not expect substantial variation under the newly claimed hybridization conditions and 75% identity is even more narrowly constrained. Therefore the breadth of the claims is not unduly broad.

Thus given that most if not all of the Wands factors weigh in the favor of Applicants, the invention as claimed would not require undue experimentation by one of skill in the art to make and use the invention commensurate with the scope of the invention. Applicants respectfully request that the Examiner withdraw the rejection of claims 20-33, 39-40, 42-46, 52, and 54-55 based upon 35 U.S.C. § 112, first paragraph.

10

Docket No.: 532792001001

Claim Rejections - 35 USC § 112, first paragraph, Written Description

The Examiner has rejected claims 20-33, 39-40, 42-46, 52 and 54-55 under 35 U.S.C. 112, first paragraph, as containing subject matter not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors had possession of the claimed invention. The Examiner has asserted that the specification does not adequately disclose the structural features common to members of the claimed genus of polynucleotides because the sequence is claimed only by its function.

Applicants respectfully disagree with the Examiner's grounds for rejection and the above statements. However, in order to facilitate prosecution in this case applicants have amended the pending claims, without prejudice or disclaimer, to include a structural limitation linked to the claimed function of the CDR1 gene. Specifically, claims 20-33, 39-40, 42-46, 52, and 54-55 are now limited to nucleic acids that are at least 75% identical to the sequence of SEQ ID NO:1. One of skill in the art would recognize that the inventors had possession of the invention given the structural limitation now provided. The specification provides guidance as to identification of homologs from other plants likely to fall within the 75% identity starting on page 27, line 20 of the specification. One of skill in the art would recognize that homologous genes having 75% identity from other plants almost certain to have the claimed function particularly in light of the skill in the art as of filing the priority document for this patent application. In the present case, Applicants clearly have adequately described the claimed invention and had possession of the invention as of filing the application. Therefore, Applicants respectfully request that the Examiner withdraw the rejection of claims 20-33, 39-40, 42-46, 52, and 54-55 based upon 35 U.S.C. § 112, first paragraph. Applicants respectfully assert that new claims 56-59 also meet the requirements of 35 U.S.C. § 112, first paragraph.

Claim Rejections - 35 USC § 102(b)

The Examiner has rejected claims 20-33, 39-40, 42-46, 52, and 54-55 under 35 U.S.C. 102(b) as being anticipated by Ryals *et al.* (US 5,614,395). The Examiner has asserted that the term "CDR1" has a broad enough definition to cover the teachings of Ryals *et al.*

The rejection is rendered most by the amendment to the claims. In order to anticipate, a reference must teach all elements of a claimed invention. Amended claims 20, 31, 39, and 52

11

Docket No.: 532792001001

include a polynucleotide or nucleic acid encoding the polypeptide having 75% identity to SEQ ID NO:1. Furthermore, claims 21-30, 32-33, 40, 42-46, and 54-55 depend from the amended claims and thereby include the limitation. Ryals *et al.* fail to teach a polynucleotide or nucleic acid encoding the polypeptide having 75% identity to SEQ ID NO:1, therefore it does not anticipate the claimed invention.

Applicants respectfully request that the Examiner withdraw the rejection of claims 20-33, 39-40, 42-46, 52, and 54-55 based upon 35 U.S.C. § 102(b).

Claims Free From the Prior Art

Applicants thank the Examiner for noting that claims 41 and 53 are free from prior art.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to <u>Deposit</u> Account No. 03-1952 referencing docket no. 532792001001.

Dated: September 3, 2004

Respectfully submitted,

Michael R. Ward

Registration No.: 38,651

MORRISON & FOERSTER LLP

By Michael Eller

425 Market Street

San Francisco, California 94105

(415) 268-7000

Attorneys for Applicant